(1) The application is otherwise approvable.

(2) The application contains the results of studies to determine the compatibility of the large volume parenteral drug product's plastic container with drugs that may be added regularly to the parenteral delivery system.

(h) After February 13, 1979, the Food and Drug Administration shall approve a new drug application for a drug product intended to be added to a parenteral delivery system that includes a large volume parenteral drug product for intravenous use in humans that is packaged in a plastic immediate container if all of the following conditions are met:

(1) The application is otherwise approvable.

(2) The application contains the results of studies to determine the compatibility of the additive drug product with the plastic immediate container of marketed large volume parenteral drug products for intravenous use in humans.

(i) Holders of new drug applications for large volume parenteral drug products that are subject to this section and who must submit supplements under § 314.70(c)(2) of this chapter to provide for the labeling required under paragraph (f) of this section may put the labeling into use without advance approval by the Food and Drug Administration.

(j) This section does not apply to a biological product licensed under the Public Health Service Act of July 1, 1944 (42 U.S.C. 201).

[43 FR 58562, Dec. 15, 1978, as amended at 50 FR 8996, Mar. 6, 1985; 55 FR 11578, Mar. 29, 1990]

EFFECTIVE DATE NOTE: For a document staying the effectiveness of § 310.509 (g) and (h), see 44 FR 14540, Mar. 13, 1979.

§ 310.510 Use of aerosol drug products containing zirconium.

(a) Aerosol products containing zirconium have been used in over-the-counter drug products as antiperspirants. Based upon the lack of toxicological data adequate to establish a safe level for use and the adverse benefit-to-risk ratio, such aerosol products containing zirconium cannot be considered generally recognized as safe for use in drug products. The benefit from using aerosol drug products containing zirconium is insignificant when compared to the risk. Safer alternative antiperspirant products are available.

(b) Any aerosol drug product containing zirconium is a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act for which an approved new drug application pursuant to section 505 of the act and part 314 of this chapter is required for marketing.

(c) Clinical investigations designed to obtain evidence that any aerosol drug product containing zirconium is safe for the purpose intended must comply with the requirements and procedures governing the use of investigational new drugs set forth in part 312 of this chapter.

(d) Any such drug product introduced in interstate commerce after September 15, 1977 that is not in compliance with this section is subject to regulatory action.

[42 FR 41376, Aug. 16, 1977, as amended at 55 FR 11579, Mar. 29, 1990]

§ 310.513 Chloroform, use as an ingredient (active or inactive) in drug products.

(a) Chloroform has been used as an ingredient in drug products, such as cough preparations, liniments, and toothpastes. Although considered safe for many years, recent information has become available associating chloroform with carcinogenic effects in animals. Studies conducted by the National Cancer Institute have demonstrated that the oral administration of chloroform to mice and rats induced hepatocellular carcinomas (liver cancer) in mice and renal tumors in male rats.

(b) Any drug product containing chloroform as an ingredient is a new drug within the meaning of section 201(p) of the act and misbranded and is subject to regulatory action under sections 301, 502, and 505 of the act. Any drug product containing chloroform in residual amounts from its use as a processing solvent during manufacture, or as a byproduct from the synthesis of an ingredient, is not, for the purpose of this section, considered to contain chloroform as an ingredient.